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EXAMINER

MALLARI, PATRICIA C

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	09/978,345	Applicant(s)	M J
Examiner	Patricia C. Mallari	Art Unit	3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 16 October 2001 .

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-32 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 16 October 2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.

4) Interview Summary (PTO-413) Paper No(s). _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: when ranges are given, “~” should be replaced with “-”. Appropriate correction is required.

Claim Objections

Claim 1 is objected to because of the following informalities: “change” on the last line of the claim should be replaced with “changes”. Appropriate correction is required.

Claims 2-5 and 19 are objected to because of the following informalities: all instances of “~” should be replaced with “-“. Appropriate correction is required.

Claims 4, 5, and 19 are objected to because of the following informalities: “palmal” on line 4 of claim 4, line 6 of claim 5, and line 6 of claim 19 should be replaced with “palmar”. Appropriate correction is required.

Claim 9 is objected to because of the following informalities: “possess” on line 6 of the claim should be replaced with “possesses”; “comparing” on line 10 of the claim should be replaced with “compared”. Appropriate correction is required.

Claim 17 is objected to because of the following informalities: “includes, at least,” on line 10 (step d) of the claim should be replaced with “including at least”. Appropriate correction is required.

Claim 22 is objected to because of the following informalities: “the pressure sensing” on line 2 of the claim should be replaced with “and the pressure sensing”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification lacks adequate description of detecting the change of the pulse signal of the radial artery by measuring a variation of the external pressure of the radial artery caused by the pulsation of the radial artery in the wrist.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-32 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitations "the wrist", "the position", and "the tendons" on line 2 of the claim; "the radial artery" and "the radius" on line 3 of the claim; and "the change of pulse signal" on line 5 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claims 2-5 recite the limitations "the dorsal side of the wrist" and "the dorsal side of the hand" on lines 2-3 of each claim. There is insufficient antecedent basis for these limitations in the claims. Claims 3 and 5 also recite the limitation "the medial side of body" on line 4 of each claim. Claims 4 and 5 also recite the limitations "the central line

of the hand" and "the central line of the palmal side of the wrist" on lines 3-4 claim 4 and lines 4-6 of claim 5. There is insufficient antecedent basis for these limitations in the claims.

Claims 6-8 and 10-15 are written in improper method claim format. Method claims must be active. For example, claim 6 should read "The method as defined in claim 1, wherein said step of detecting the change of the pulse signal of the radial artery includes measuring the variation of said external pressure of the radial artery caused by the pulsation of radial artery in the wrist."

Claim 6 recites the limitations "the variation" on line 2 of the claim and "the pulsation" on line 3 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 7 and 8 recite the limitations "the change of volume" on line 2 of each claim and "the pressure area" on line 3 of each claim. Claim 8 also recites the limitations "the optimal pulse signal" on lines 4-5 of the claim and "the volume change of the pulse signal" on line 5 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 9 recites the limitations "the maximum oscillation" on line 6 of the claim; "the possible means blood pressure" on lines 7-8 of the claim; "the range" on line 8 of the claim; "the possible systolic blood pressure" on lines 8-9 of the claim; "the subject" on line 9 of the claim; "the amplitude" on lines 9 and 10 of the claim; "the largest" on line 10 of the claim; "the pressure" on line 14 of the claim; and "the maximum amplitude"

and “the bladder pressures” on line 15 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 10 recites the limitations “the position of the optimal site” on line 1 of the claim; “the pressure area of the pressure bladder” on line s 1-2 of the claim; “the position of the bladder” on lines 2-3 of the claim; and “the display” on line 3 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 12 recites the limitations “the oscillometric method” on line 2 of the claim and “the mean blood pressure “ on line 3 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 13 recites the limitations “the process” and the vascular unloading method” on lines 2-3 of the claim and “ the instantaneous blood pressure” on line 3 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 14 recites the limitation “exchangeably” on line 2 of the claim. The claim is indefinite because the term “exchangeably” is undefined. Furthermore, the claim recites the limitations “the process of oscillometric method” on lines 2- 3 of the claim; “the mean blood pressure” on line 3 of the claim; “the process” on line 4 of the claim; “the vascular unloading method” on line 5 of the claim; and “the instantaneous blood pressure” on lines 5-6 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 15 recites the limitations “the ulnar artery” on line 4 of the claim; “the change of pulse signal of the ulnar artery” on line 5 of the claim; and “the blood pressure

of the ulnar artery" on lines 5-6 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 16 recites the limitations "the results" on lines 1 and 2 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 17 recites the limitations "the wrist" on line 2 of the claim; "the position" on lines 2-3 of the claim; "the tendons" and "the radial artery" on line 3 of the claim; "the radius" on line 4 of the claim; "the position" on line 6 of the claim; "the pulse signal" on line 8 of the claim; "the pressure" on line 11 of the claim; and "the blood pressure" on lines 13-14 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 18 recites the limitations "the dorsal side of the hand" and "the dorsal side of the wrist joint" on line 3 of the claim; "the dorsal side of the wrist" on lines 3-4 of the claim; and "the dorsal side of the forearm" on line 4 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 19 recites the limitations "the central line of the hand" on line 5 of the claim and "the central line of the palmal side of the wrist" on lines 5-6 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 20 recites the limitations "the thickness" on line 1 of the claim; "the part" on line 2 of the claim"; "the difference" and "the diameters" on line 3 of the claim; "the sinking surface" on line 4 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 22 recites the limitation "the pressure sensing surface" on lines 2-3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 23 recites the limitations "the center of said bladder wall" on line 6 of the claim and "the inside of the wall" on line 7 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 24 recites the limitation "the reflective photoelectric transducer" on line 3 of the claim"; "the center of said array" on line 8 of the claim; "the center of the bladder wall" on line 9 of the claim; "the photoelectric devices" on lines 9-10 of the claim; and "the corresponding input" on line 10 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 25 recites the limitations "the maximum oscillation" on line 4 of the claim; "the amplitude" on line 5 of the claim; "the largest" on lines 5-6 of the claim and "the amplitude" on line 6 of the claim. There is insufficient antecedent basis for these limitations in the claim. Furthermore, on line 2 of step b) it is unclear what is meant by "which the bladder pressure is higher".

Claim 26 recites the limitations "the exact position" on line 4 of the claim. There is insufficient antecedent basis for this limitation in the claim.

In claims 28-30 it is unclear whether the recited pressure feeding device and the signal processing device are those claimed originally in claim 17 or if they constitute a second pressure feeding device and signal processing device.

Claim 28 recites the limitations “the mean blood pressure” on line 3 of the claim; “the process” on line 4 of the claim; and “the oscillometric method” on lines 4-5 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 29 recites the limitations “the instantaneous blood pressure” on line 3 of the claim and “the process” and “the vascular unloading method” on line 4 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 30 recites the limitations “the mean blood pressure” on line 3 of the claim; “the process” on line 4 of the claim; “the oscillometric method” on line 5 of the claim; “the instantaneous blood pressure” on lines 5-6 of the claim; “the process” on line 6 of the claim; “the vascular unloading method” on lines 6-7 of the claim; “the connection” on lines 7-8 of the claim; and “the requisition” on the last line of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim 31 recites the limitation “the pulse signal of ulnar artery” on lines 2-3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 32 recites the limitation “the results of radial arterial blood pressure” on line 2 and lines 2-3 of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 18- 21, 23-27, and 31 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 18 recites the limitation "its length and width covering at least the dorsal side of the hand, the dorsal side of the wrist joint, the dorsal side of the wrist, and the dorsal side of the forearm close to the elbow". Claim 19 recites the limitation "the shape of the curved board forms an angle between the dorsal side of the wrist and the dorsal side of the hand". Claim 21 recites the limitations "two ends of an opening of said strap opened at the backside of the wrist" and "pressure bladder which closes to the wrist". Claim 23 recites the limitation "pressure bladder which closes to the wrist" on the last line of the claim. Claim 24 recites the limitation " pressure bladder which closes to the wrist". In this case, the patient's body (wrist) is non-statutory subject matter and cannot positively can be claimed. Claim 31 recites the limitation " a pressure bladder . . . that may be placed on the wrist skin". In each case, the patient's body or body part (for example, the wrist) is non-statutory subject matter and cannot positively be claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 6-8, 17, 21, and 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hon (WO 97/12542) in view of Tochikubo. Hon teaches a blood pressure monitoring device 10 comprising a cuff 12 with internal bladder 14 that is inflated with air by a pump 16 to tension the cuff to compress the radial artery of the patient. A sensor 20 is located on the interior surface 18 of the cuff 12 and is

positioned to correspond with the radial artery when the cuff 12 is placed around the arm of a patient. The sensor 20 has a membrane 21 contacting the exterior of the internal bladder 14 to communicate signals obtained from the artery to the monitoring unit 40 via the internal bladder 14. Sensor 20 may measure blood flow sounds and the peaks of the pulse wave and blood flow sounds simultaneously. An arm board 30 extends from the cuff 12 to hold the patient's arm in a stable position. In figure 3, the board 30 is shown holding the patient's wrist in a flexed position; however, any angle of flexion may be used (figs. 1-3). Such a position as that shown in figure 3 would raise the tendons near the radial artery and cause the radial artery to be close to the radius. Hon fails to describe the method of determining blood pressure used.

Tochikubo teaches a sphygmomanometer cuff 10 composed of a plated 10a with an inflatable air bag 10d secured inside the inside cloth 10c. A pump 24 and pressure sensor 20 are used to control the inflation the bag 10d. Photoelectric sensor 12 and photocoupler 12a are fixed to the outer surface of the bag member 10 g of air bag 10a. A plurality of optical range sensors 12 may be disposed along the circumferential direction, in which case, the one with the largest output may be selected by comparing the output values of the respective sensors 12. The minimum and maximum blood pressures are determined from the photoelectric volumetric pulse wave signals. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the method of Tochikubo as the blood pressure determination for the monitoring device of Hon, since Hon specifies that blood pressure is determined, and Tochikubo describes such a method of determining blood pressure.

Claims 1, 2, 6, 12, 14, 17, 21, 22, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hon ('542) in view of Aung et al. Hon teaches a blood pressure monitoring device 10 comprising a cuff 12 with internal bladder 14 that is inflated with air by a pump 16 to tension the cuff to compress the radial artery of the patient. A sensor 20 is located on the interior surface 18 of the cuff 12 and is positioned to correspond with the radial artery when the cuff 12 is placed around the arm of a patient. The sensor 20 has a membrane 21 contacting the exterior of the internal bladder 14 to communicate signals obtained from the artery to the monitoring unit 40 via the internal bladder 14. Sensor 20 may measure blood flow sounds and the peaks of the pulse wave and blood flow sounds simultaneously. An arm board 30 extends from the cuff 12 to hold the patient's arm in a stable position. In figure 3, the board 30 is shown holding the patient's wrist such that it is flexed but neither parallel nor perpendicular to the forearm; however, any other angle may also be used (figs. 1-3). Hon fails to describe the method of determining blood pressure used.

However, Aung teaches an inflatable blood pressure cuff 10 with pressure sensor 12 and air pump 14. During operation, pressure sensor 12 produces a pressure signal SP, from which a cuff pressure signal SK and a pulse wave signal SM are determined. In the blood pressure determination routine S7, first a mean blood pressure is determined at the time of detection of a pulse having greatest amplitude during the slow decrease of cuff pressure. CPU 30 determines systolic blood pressure as a cuff pressure at the time of an inflection point of the amplitudes, where the point is on a higher-pressure side of the mean blood pressure, and a diastolic blood pressure as a

cuff pressure at the time of an inflection point of the amplitudes where the point is located on a lower-side of the mean blood pressure (figs. 1 & 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the method of Aung et al. as the blood pressure determination for the monitoring device of Hon, since Hon specifies that blood pressure is determined, and Aung describes such a method of determining blood pressure.

Claims 1, 2, 6, 7, 13, 14, 17, 18, 21, 23, and 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hon ('542) in view of Penáz. Hon teaches a blood pressure monitoring device 10 comprising a cuff 12 with internal bladder 14 that is inflated with air by a pump 16 to tension the cuff to compress the radial artery of the patient. A sensor 20 is located on the interior surface 18 of the cuff 12 and is positioned to correspond with the radial artery when the cuff 12 is placed around the arm of a patient. The sensor 20 has a membrane 21 contacting the exterior of the internal bladder 14 to communicate signals obtained from the artery to the monitoring unit 40 via the internal bladder 14. Sensor 20 may measure blood flow sounds and the peaks of the pulse wave and blood flow sounds simultaneously. An arm board 30 extends from the cuff 12 to hold the patient's arm in a stable position. In figure 3, the board 30 is shown holding the patient's wrist such that it is flexed but neither parallel nor perpendicular to the forearm; however, any other angle may also be used (figs. 1-3). Hon fails to describe the method of determining blood pressure used.

However, Penáz provides a pressure cuff 1, usable over any appropriate region, such as a finger, forearm, and temporal region, with a plethysmographic gauge 2 of the

arterial volume and surrounds the measured zone 3. Gauge 2 connects through a summing member 4 to amplifier 5, which is connected to a voltage-pressure transducer 6. The cuff 1, member 4, amplifier 5, and transducer 6 make up the loop of the basic servo system that maintains the artery volume of the measured zone 3 at a constant value by immediate pressure changes in the pressure cuff 1. The pressure in cuff 1 corresponds to instantaneous intraarterial pressure when the artery is compressed so that the vascular wall has a zero tension. The gauge 2 utilizes a light source 10 and light sensor 11 on the inner sheet of cuff 1 (figs. 1 & 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the method of Penáz as the blood pressure determination for the monitoring device of Hon, since Hon specifies that blood pressure is determined, and Penáz describes such a method of determining blood pressure.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hon ('542) in view of Tochikubo as applied to claims 1, 2, 6-8, 17, 21, and 23 above, and further in view of Hon et al. ('422). Hon ('542), as modified, lacks a wrist holding device covering the dorsal side of the hand, the dorsal side of the wrist joint, the dorsal side of the wrist, and the dorsal side of the forearm. However Hon et al. ('442) discloses a blood pressure monitoring apparatus 10 that uses a hand restraining device 80 that extends over the dorsal side of the hand, wrist, and forearm (fig. 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to extend the arm board of Hon ('542) in view of Tochikubo over the dorsal side of the hand, wrist, and forearm of a patient as a mere matter of design choice.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hon ('542) in view of Tochikubo as applied to claims 1, 2, 6-8, 17, 21, and 23 above, and further in view of Chesney et al. (Hon ('542), as modified, lacks a wrist holding device covering the dorsal side of the hand, the dorsal side of the wrist joint, the dorsal side of the wrist, and the dorsal side of the forearm. However Chesney teaches a blood pressure measurement device that utilizes different embodiments of a wrist stabilizer. In one embodiment, the wrist stabilizer 900, shown in Figure 9, extends over the dorsal side of the patient's hand, wrist, and forearm, and is also shown as being thicker at the part passing over the dorsal side of the wrist. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the apparatus of Hon ('542) in view of Tochikubo with that of Chesney in order to further stabilize the radial artery and bring it near the skin in order while holding the patient's hand and fingers in a relaxed position to obtain a good blood-pressure waveform.

Allowable Subject Matter

Claims 3-5, 9-11, 15, 16, 19, 24-27 and 30-32 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph and/ or 35 U.S.C. 101, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent No. 4850369 to Yamasawa

US Patent No. 5054495 to Uemura et al.

US Patent No. 5913826 to Blank

US Patent No. 6231517 Forstner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (703) 605-0422. The examiner can normally be reached on Mon-Fri 9:30 am-7:00 pm (alternate Fri. off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (703) 308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-8117 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

pcm

February 21, 2003

Patricia Mallari

Robert L. Nasser

ROBERT L. NASSER
PRIMARY EXAMINER